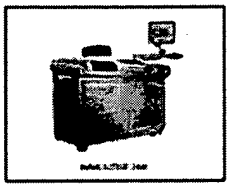
# Immulite® 2000



## General Information

| | |
|---|---|
| **Vendor** | **Diagnostic Products Corporation** |
| **Item** | **Immulite® 2000** |
| **Features** | Throughput of up to 200 tests/hour, 24 resident assays, proprietary on-board c automatic re-assay of out of range samples, reflex testing for additional clinical primary, secondary and micro sampling, STAT capability, open architecture to i lab automation or work cell configurations, clot detection, proprietary wash tecl sensitivity, third generation assays, extensive routine as well as esoteric menu clinical diagnostic information, unique user interface software for enhanced ope board refrigeration, automatic monitoring of reagents, supplies and waste. |
| **Approval** | Worldwide |
| **Product Number** | Inquire |
| **Software** | Inquire |
| **Type of System** | Inquire |
| **Throughput Rate** | 200 tests/hour |
| **Process Time** | Inquire |
| **Available tests** | Inquire |
| **Continuous, random, and STAT access** | Inquire |
| **Automation** | Inquire |
| **Clot and liquid level detection** | Inquire |
| **List Price** | Inquire |

## Product Description

The Immulite 2000, a continuous random-access analyzer, with a processing throughput of : hour, has been designed specifically for optimum efficiency and consolidation in medium- an laboratories.

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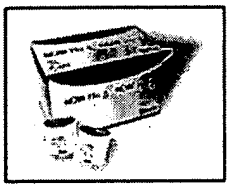

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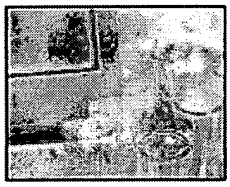

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**Vendor Contact Information**

**Diagnostic Products Corporation**

Customer Service: **(800) 372-1782**

Web site: http://www.dpcweb.com/

NOTE: Medcompare disclaims any information on this site. Price information is approximate list price ar may vary.

Journal of Clinical Endocrinology & Metabolism, Vol 67, 465-473,




ARTICLES

# Modulation of serum follicle-stimulating hormone bioactivity and isoform distribution by estrogenic steroids in normal women and in gonadal dysgenesis

**V Padmanabhan, LL Lang, J Sonstein, RP Kelch and IZ Beitins**
Department of Pediatrics, University of Michigan, Ann Arbor 48109.

To determine the influence of estrogenic steroids on serum FSH bioactivity (B) and immunoreactivity (I) and the FSH isoform distribution profiles, we studied normal women during ovulatory menstrual cycles and a patient with gonadal dysgenesis treated with diethylstilbestrol (DES). Four women with ovulatory menstrual cycles, as judged from their serum immunoreactive LH, FSH, progesterone, and estradiol profiles in daily blood samples, had a significant increase in the mean FSH B/I ratio (P less than 0.05) during the midcycle phase of their menstrual cycles. Similarly, in the patient with gonadal dysgenesis the FSH B/I ratio rose significantly (P less than 0.05) after 3 weeks of DES treatment and declined during the posttreatment period. In five additional normal women, serum obtained during the follicular, midcycle, and luteal phases of their menstrual cycles was chromatofocused, and the FSH isoform distribution pattern determined. Sera obtained from the patient with gonadal dysgenesis before, during, and after DES administration were pooled and studied similarly. Chromatofocusing of a human pituitary tumor extract allowed for determination of the FSH B/I ratio in different pH ranges. The highest FSH B/I ratio was found in the more basic fractions (pH range 5.6-6.0) compared to the acidic fractions. During both the midcycle phase of the normal cycles and the DES administration period in the studies of the patient with gonadal dysgenesis, there was a shift of the FSH isoforms (as measured by immunoassay) to the basic pH range. In contrast, the mid- to late luteal phase samples, which had low B/I ratios, had an increase in FSH isoforms in the acidic pH range (less than 4.8). Similarly, in the patient with gonadal dysgenesis FSH isoforms in the basic range were more abundant during the DES treatment period than in the pre- or posttreatment serum pools. Therefore, it appears that endogenous and exogenous estrogenic stimulation alters FSH isoform distribution such that FSH isoforms that are more basic and have increased biological activity are secreted.

Anobile, C.J., Talbot, J.A., McCann, S.J. *et al.* (1998) Glycoform composition of serum gonadotrophins through the normal menstrual cycle and in the post-menopausal state. *Mol. Hum. Reprod.*, **4**, 631–639. [Abstract]

Baenziger, J.U. and Green, E.D. (1988) Pituitary glycoprotein hormone oligosaccharides: structure, synthesis and function of the asparagine-linked oligosaccharides on lupotropin, follitropin and thyrotropin. *Biochim. Biophys. Acta*, **947**, 287–306.[ISI][Medline]

Bergh, C., Howles, C.M., Borg, K. *et al.* (1997) Recombinant human follicle stimulating hormone (r-hFSH; Gonal-F) versus highly purified urinary FSH (Metrodin HP): results of a randomized comparative study in women undergoing assisted reproductive techniques. *Hum. Reprod.*, **12**, 2133–2139.[Abstract]

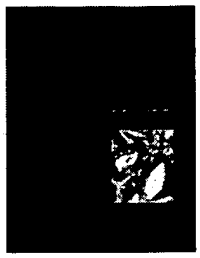
Chappel, S.C. (1995) Heterogeneity of follicle stimulating hormone: control and physiological function. *Hum. Reprod. Update*, **1**, 479–487.[Abstract]

## Abstract



**Clinical Endocrinology**
Volume 51 Page 681 - December 1999
doi:10.1046/j.1365-2265.1999.00823.x
Volume 51 Issue 6





# Do immunoassays differentially detect different acidity glycoforms of FSH?

*Robert L. Oliver, John W. Kane, Annelise Waite, John W. M. Mulders & William R. Robertson*

**OBJECTIVE**

The possibility of the carbohydrate residues of glycoproteins affecting their recognition in immunoassays is an important and unresolved issue. This study looked for evidence of differential recognition of FSH glycoform preparations, of variable isoelectric point (pI) and known molarity, using three routine assays employing different antibody configurations.

**DESIGN**

Seven glycoform preparations with differing pI bands (between 3.8 and 5.5) were produced by isoelectric focusing of recombinant human FSH and the molecular weights determined by mass spectroscopy. Three concentrations of each glycoform were assayed and the results expressed relative to unfractionated material. From the relative responses, recognition differences between the assay methods and between the glycoform preparations were investigated.

**MEASUREMENTS**

Three routine assays were employed: the commercially available Amerlite® enzyme immunoassay and Delfia® immunofluorometric assay, together with an in-house competitive two-site radioimmunoassay (RIA).

**RESULTS**

Overall, the three assays gave the same relative responses for equivalent glycoforms, with the only exceptions involving small differences between some assay pairs for the fractions at the extremes of the pI range investigated. Within each assay type, differences



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*Correspondence to:* J. W. Kane, Department of Medicine (Clinical Biochemistry), Clinical Sciences Building, Hope Hospital, Eccles Old Road, Salford M6 8HD, UK.

($P < 0.05$) of up to 33% existed between glycoforms of different pI, however, these differences showed no patterns or trends across the entire acidity range examined.

**CONCLUSIONS**

Between the assay methods investigated in this study, few differences exist in the recognition of individual pI bands of FSH when expressed relative to a common unfractionated standard. Differences were apparent in the recognition of the different acidity glycoforms within each assay method, however, these were small and unlikely to be of clinical significance.

**To cite this article**
Oliver, Robert L., Kane, John W., Waite, Annelise, Mulders, John W. M. & Robertson, William R. (1999)
Do immunoassays differentially detect different acidity glycoforms of FSH?.
*Clinical Endocrinology* **51** (6), 681-686.
doi: 10.1046/j.1365-2265.1999.00823.x

References Full Text Article PDF [268KB]

Entry 10 of 30 File: USPT Nov 3, 1998

DOCUMENT-IDENTIFIER: US 5830680 A
TITLE: Unitary sandwhich enzyme immunoassay cassette device and method of use

CLAIMS:

6. The cassette of claim 1 wherein said first capture antibody layer comprises a first antibody that specifically binds to an analyte selected from the group consisting of hCG, prostate-specific antigen, creatine phosphokinase, troponin, myoglobin, light-chain myosin, fibrinogen, thyroid stimulating hormone, FSH, hepatitis antigen, and a viral protein.

13. A device for performing an enzyme sandwich immunoassay for at least a first predetermined analyte, said device comprising a reaction vessel divided into first and second chambers by a microporous membrane support, such that

(a) said first chamber is capable of containing at least a first enzyme-labeled antibody, wherein said first enzyme-labeled antibody specifically binds to said first analyte and said labeling enzyme is capable of reacting with a substrate to produce an electrochemically detectable product;

(b) said second chamber is capable of containing said substrate; and

(c) a side of said separating microporous membrane support facing said first chamber is coated with

(i) a conductive metal layer and

(ii) at least a first capture antibody layer immobilized over said conductive metal layer in at least a first spatially distinct area of said microporous membrane support,

wherein said conductive metal layer functions as an electrode to detect, directly or indirectly, said electronically detectable product and said microporous membrane support is permeable to said substrate.

18. The device of claim 13 wherein said first capture antibody layer comprises a first antibody that specifically binds to an analyte selected from the group consisting of hCG, prostate-specific antigen, creatine phosphokinase, troponin, myoglobin, light-chain myosin, fibrinogen, thyroid stimulating hormone, FSH, hepatitis antigen, and a viral protein.

25. The method of claim 23 wherein said first capture antibody layer comprises a first antibody which specifically binds to an analyte selected from the group consisting of hCG, prostate-specific antigen, creatine phosphokinase, troponin, myoglobin, light-chain myosin, fibrinogen, thyroid stimulating hormone, FSH, hepatitis antigen, and a viral protein.

# WEST Search History

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DATE: Wednesday, February 01, 2006

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|---|---|---|---|
| | | *DB=PGPB,USPT,USOC,EPAB,JPAB,DWPI,TDBD; PLUR=YES; OP=OR* | |
| ☐ | L1 | diagnostic.asn. and products.asn. and corporation.asn. | 7 |
| ☐ | L2 | l1 and two | 7 |
| ☐ | L3 | l2 and (multiple or plurality or second or more) | 7 |
| ☐ | L4 | l2 and several | 7 |
| ☐ | L5 | l4 and sandwich | 4 |
| ☐ | L6 | (first same second same sandwich).ti,ab,clm. | 6230 |
| ☐ | L7 | L6 and (hfsh or fsh or follitropin or gonadotropins or tropins or lh or hlh or hcg or cg or h-cg or corionic tsh or rfsh).ti,ab,clm. | 30 |
| ☐ | L8 | $menopause.ti,ab,clm. | 1156 |
| ☐ | L9 | L8 and (glycoforms or glyco-forms or isoforms or isoform or glycosylation or glycosylated or glyco$).ti,ab,clm. | 53 |
| ☐ | L10 | l8 | 1156 |
| ☐ | L11 | $menopause.ti. | 180 |
| ☐ | L12 | L11 not l9 | 175 |
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| ☐ | L16 | total.clm. and ($form.clm. or glycoform$.clm. or glycoprotein.clm. or glycopeptide.clm.) | 81494 |
| ☐ | L17 | total.clm. same(hfsh or fsh or follitropin or gonadotropins or tropins or lh or hlh or hcg or cg or h-cg or corionic tsh or rfsh).clm. | 67 |
| ☐ | L18 | detect$.clm. and different$.clm. and (glycoforms or glyco-forms or isoforms or isoform or glycosylation or glycosylated).clm. | 184 |
| ☐ | L19 | L18 and (gonadotropin or lh or hlh or hcg or fsh or follitropin or leukotropin or hfsh or follicle).clm. | 8 |
| ☐ | L20 | method.clm. and posttranslation$.clm. | 44 |
| ☐ | L21 | L20 and hormone.clm. | 5 |

END OF SEARCH HISTORY

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**Search Results** - Record(s) 1 through 8 of 8 returned.

☐ 1. 20040219621. 17 Feb 04. 04 Nov 04. Test methods and devices. Butlin, Lorraine D., et al. 435/7.93; G01N033/53.

☐ 2. 20020045273. 03 Apr 01. 18 Apr 02. Test methods and devices. Butlin, Lorraine D., et al. 436/518; 435/7.93 G01N033/53 G01N033/537 G01N033/543.

☐ 3. 20020042149. 03 Apr 01. 11 Apr 02. Test methods and devices. Butlin, Lorraine D., et al. 436/518; 702/19 G01N033/543 G06F019/00 G01N033/48 G01N033/50.

☐ 4. JP02001349892A. 02 Apr 01. 21 Dec 01. TEST METHOD AND DEVICE. BUTLIN, LORRAINE DIANE, et al. G01N033/543; C07K016/26 C12N015/02 G01N033/53 G01N033/577 C12N005/10 C12P021/08.

☐ 5. JP02001349891A. 02 Apr 01. 21 Dec 01. TEST METHOD AND DEVICE. BUTLIN, LORRAINE DIANE, et al. G01N033/543; C07K016/18 C12N015/02 C12P021/08 G01N033/53 G01N033/577.

☐ 6. EP001143250A2. 02 Apr 01. 10 Oct 01. Test methods and devices for analyte isoforms. BUTLIN, LORRAINE DIANE, et al. G01N033/543; G01N033/76 G01N033/577 C07K016/26.

☐ 7. EP001143249A2. 02 Apr 01. 10 Oct 01. Test methods and devices for analyte isoforms. BUTLIN, LORRAINE DIANE, et al. G01N033/543; G01N033/76 G01N033/577 C07K016/26.

☐ 8. EP 1143250A. Differentiating iso-forms of an analyte using two assays, one independent of and the other dependent on the iso-form present, useful for distinguishing gonadotrophin iso-forms in diagnosis of the menopause. BUTLIN, L D, et al. C07K016/26 C12N005/10 C12N005/12 C12N015/02 C12P021/04 C12P021/08 G01N033/48 G01N033/50 G01N033/53 G01N033/541 G01N033/543 G01N033/577 G01N033/74 G01N033/76 G01N033/96 G06F019/00.

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| Term | Documents |
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| BUTLIN | 262 |
| BUTLINS | 0 |
| COLEY | 1898 |
| COLEYS | 3 |
| CONTEMPORANEOUS$ | 0 |
| CONTEMPORANEOUS | 5229 |
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| CONTEMPORANEOUSLV | 4 |
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Prev Page Next Page Go to Doc#

L17: Entry 32 of 67 File: PGPB Jul 11, 2002

PGPUB-DOCUMENT-NUMBER: 20020090638
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20020090638 A1

TITLE: Stabilization of particles and reduction of sample discordance in immunoassays using casein coating of particles

PUBLICATION-DATE: July 11, 2002

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY |
|---|---|---|---|
| Ni, Wei-Chao | Foxboro | MA | US |
| Eustace, Daniel W. | North Attleboro | MA | US |
| Chang, Steve Chin-Shen | Franklin | MA | US |

US-CL-CURRENT: 435/6; 436/528

CLAIMS:

We claim:

1. A process for using solid phases coated with casein in binding assays, said solid phases being combined directly or indirectly to an active ingredient used in said binding assay.

2. The process of claim 1 in which said solid phase is a paramagnetic particle and said binding assay is an immunoassay or a gene probe assay.

3. The process of claim 1 in which said active ingredient is selected from the group consisting of antigens, antibodies, nucleic acids, nucleic acid polymers, and other receptors.

4. The process of claim 1 in which said casein is in the form of sodium caseinate or potassium caseinate.

5. A process for making casein-coated paramagnetic particles containing active ingredients used in binding assays, said process comprising mixing casein with paramagnetic particles and active ingredients, said mixing taking place at 30-60.degree. C. for 5-180 hours to form casein-coated paramagnetic particles, said particles optionally containing one or more components which act as an intermediary reactive entity to assist in the addition of an active ingredient needed in said binding assay.

6. The process of claim 5 in which said paramagnetic particles had previously been coupled with said active ingredients.

7. The process of claim 5 wherein said components are selected from the group

consisting of biotin, avidin, and streptavidin.

8. The process of claim 5 in which said active ingredients are selected from the group consisting of antigens, antibodies, nucleic acids and nucleic acid polymers.

9. The process of claim 5 in which said casein is in the form of sodium caseinate or potassium caseinate.

10. The process of claim 5 in which said mixing takes place at 37-50.degree. C. for 14-144 hours.

11. Paramagnetic particles coated with casein for use in binding assays, said coated particles comprising 0.05-4.0 grams of casein per gram of paramagnetic particle.

12. The paramagnetic particles of claim 11 comprising 0.15-3.2 grams of casein per gram of paramagnetic particles.

13. The paramagnetic particles of claim 11 comprising 0.78-1.2 grams of casein per gram of paramagnetic particles.

14. The paramagnetic particle of claim 11 in which said casein is in the form of sodium caseinate or potassium caseinate.

15. The process of claim 2 in which said binding assay is for an analyte selected from the group consisting of ferritin; Tuptake; thyroxine; 3, 3', 5-triiodothyronine; free 3, 3', 5-triiodothyronine; total human chorionic gonadotropin; CA 19-9; and testosterone.

16. The process of claim 2 in which interference caused by non-specific binding is reduced.

17. The process of claim 2 in which interference caused by sample discordance is reduced.

18. The process of claim 2 in which stability is improved due to the addition of casein.

19. The process of claim 2 in which said paramagnetic particle is also coated with bovine serum albumin.

Previous Doc Next Doc Go to Doc#